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10/726,024	12/02/2003	Manesh Dixit	141-239A	2662

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,024	DIXIT ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 71-84 are pending and under examination herein.

Response to Arguments

Applicant's removal of the reference to a figure in the claim is sufficient to overcome the 35 USC 112, second paragraph rejection.

Applicants argue over the 35 USC 103 rejection over Mehta et al. in view of Mulye and Beiman et al. Applicants argue that Mehta et al. does not teach or suggest a single compressed tablet core surrounded by a single enteric coating and teaches away from the present invention by stating that sustained release formulations of methylphenidate have been shown to have lower efficacy than conventional dosage forms. Applicants argue that Mulye provides no motivation to modify the teachings of Mehta because Mulye teaches slow release of the drug at a pH of about 1.2 – 4.5 and a rapid release in pH 7.4 as opposed to the present invention which slowly releases methylphenidate at a pH of 7.5. Likewise, Applicants argue that Beiman teaches enteric polymers that dissolve at a pH of 5.0 or higher and does not provide motivation to combine.

In response to the above arguments, it was noted in the previous Office Action that Mehta et al. does not teach a single compressed tablet surrounded by a single enteric coating. However, Mehta et al. was used to teach a single dosage unit with two time-separated doses of methylphenidate, including an immediate release and a delayed release. Mehta's discussion of sustained release formulations of

methylphenidate having lower efficacy than conventional dosage forms is in the background section and is the rationale for Mehta's invention. Mehta clearly teaches a formulation with an immediate release and a delayed release of the drug.

It is noted that the arguments regarding the pH in the Mulye reference, it is noted that Mulye is delivering the drug to be released at certain pH's in the stomach and intestines. Mulye discusses that the enteric polymers is soluble in pH of 6.0 to about 7.5 (Col. 6, lines 8-21). Therefore Mulye discusses release of the drug in a pH environment above 6.0, including 7.5. The same is true for Beiman, in which Beiman teaches drug release in environments with different pH's and that the enteric polymer coating does not dissolve in the stomach but dissolves in pH's of 5.0 or higher, which includes 7.5.

It is further noted that Applicants have amended the claims which will be dealt with accordingly below.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that the claims contain both "consisting of" language as well as "comprising" language that is confusing. Further, the claims

include optional ingredients, which contradict the claim language of a composition consisting of. Appropriate correction to the ambiguity of the claims is required. The claims are being examined as they read on compositions comprising the elements listed in each of the claims.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 71-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (U.S. Patent 5,837,284) in view of Mulye (U.S. Patent 6,475,493) and Beiman et al. (U.S. Patent 6,312,728).

Mehta et al. teach an improved dosing of methylphenidate hydrochloride whereby two time-separated doses are provided via a single dosage unit, in which a first group of particles provides an immediate dose of methylphenidate in an amount from about 2% to about 99% by weight and a second group of particles provides a second dose of methylphenidate in an amount from about 2% to about 75% with a binder (Col. 1, lines 13-17, Col. 3, lines 41-43, Col. 4, lines 12-14). Mehta et al. further teach a coating that delays the release of the methylphenidate (Col. 4, lines 32-36). The dosage unit is comprised of hydroxypropyl methylcellulose in an amount of 10 percent

(Col. 10, lines 42-50). Mehta et al. further teach that the maximum concentration of the first dose occurs from about 1 hour to about 3 hours after ingestion, which is followed by a period when no drug is released which lasts approximately 2-6 hours, and the second dose is released about 6 hours following administration (Col. 5, lines 37-51 and Fig. 2).

Mehta et al. does not teach a diluent in the core, processing aids, that the coating is specifically made up of enteric coating polymers, or the dissolution profile as claimed.

Mulye teaches a coating composition in a controlled release pharmaceutical composition which comprises an enteric polymer (Col. 4, lines 59-62). Active medications that can be used in the composition include methylphenidate (Col. 9, line 42). The compositions contain lactose in an amount of 2 to 70% (Col. 11, line 41) as well as colloidal silicon dioxide and magnesium stearate (Col.8, lines 4-5). Enteric polymers are present, including methacrylic acid copolymer (Col. 6, lines 28-29) and zein (Col. 12, line 22).

Similar to the teachings of Mehta et al. and Mulye, Beimen et al. teach oral dosage delivery systems comprised of a core comprising a therapeutic agent, an enteric polymer coating over said core, a coating of said therapeutic agent over enteric polymer coat and a protective coating (Col. 7, lines 5-19). Beimen et al. teach that the enteric polymer coating may also contain processing aids (Col. 8, lines 8-10). The most preferred enteric coating is Eudragit L30D-55, which is a methacrylic acid copolymer, and is applied as a 45-55 % weight aqueous solution (Col. 9, lines 11-18).

Furthermore, it is obvious to vary and/or optimize the weight of each ingredient in the controlled release formulation according to the guidance provided by Mehta et al.

and Mulye, to ensure that the proper amount of drug is released at the designated time interval. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The dissolution profile of the controlled release methylphenidate tablet as is considered a property of the controlled release tablet of the invention. If the prior art has the same components, then the properties of the composition will necessarily follow. Because the combination of the prior art renders the claimed controlled release formulation obvious, the dissolution profile would be a property of the formulation. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Mehta et al, which teach a composition for the improved dosing of methylphenidate, with Mulye and Beiman et al., which teach a controlled release pharmaceutical composition that comprises an enteric polymer that aids in delayed release of the drug. One having ordinary skill in the art would have been motivated to combine the teachings of Mehta et al. with Mulye and Beiman et al. to formulate a controlled release composition of methylphenidate to reduce abuse potential and for better patient compliance to treat nervous system disorders (as taught by Mehta et al.; Col. 1, lines 26-32).

Absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" language of the instant

claims will be construed as equivalent to "comprising". See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627